

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen Williams
Magistrate Judge

Honorable Thomas Vanaskie
(Ret.),
Special Discovery Master

**[PROPOSED] ORDER
GRANTING MOTION TO
SEAL PURSUANT TO
L.CIV.R. 5.3**

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3 (the “Motion to Seal”) filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), Princeton Pharmaceutical Inc. (“Princeton”), Huahai U.S. Inc. (“Huahai U.S.”), and Solco Healthcare US, LLC (“Solco,” and collectively with ZHP and Princeton, “the ZHP Parties”) on notice to liaison counsel for Plaintiffs; and the Court having considered the parties’ submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth

therein have been met, the Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Through discovery in this case, the ZHP Parties have produced confidential information, the public disclosure of which would affect legitimate business interests. To protect the confidentiality of this information, the parties negotiated and agreed to maintain the confidentiality of any materials produced pursuant to the Confidentiality and Protective Order (the “Protective Order”), entered by the Honorable Robert B. Kugler on June 26, 2019 ([ECF No. 139](#)).

2. The Protective Order permits the producing party to safeguard information by designating a document either “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION.” If a document does not contain one of these designations, then the information contained therein is deemed public.

3. The Protective Order defines the type of information that warrants a confidentiality designation:

The term “CONFIDENTIAL INFORMATION” as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a

competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.

“RESTRICTED CONFIDENTIAL INFORMATION” means Documents that a Party has designated as “RESTRICTED CONFIDENTIAL” in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm . . .

([Dkt. 139](#), ¶¶ 9(B), (M).)

4. The Protective Order also takes a pragmatic view of confidentiality designations given the size and scope of this litigation.

It is anticipated that the volume of documents to be exchanged by the parties during pre-trial discovery may be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as “CONFIDENTIAL INFORMATION” in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions

([Id.](#) ¶ 9(B)).

5. Pursuant to the Protective Order a party may designate a document as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. [*Id.* ¶¶ 22, 24](#). Disclosure of information designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” other than in accordance with the Order may subject the disclosing person to sanctions. [*Id.* ¶ 26](#).

6. The Protective Order further provides that any party wishing to file with the Court material designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” must file a Motion to Seal pursuant to Local Rule 5.3(c). 3. [*Id.* ¶ 31](#).

7. Pursuant to the Protective Order, the ZHP Parties move to seal the following documents designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION”, all of which are identified in the Index attached as Exhibit A to the Declaration of Kelly Bonner, Esq. (the “Index” and the “Bonner Declaration” respectively), and the Declarations of the following ZHP custodians of records with personal knowledge of the documents, attached as respectively **Exhibits B-H** thereto, which are incorporated by reference herein: Jucai Ge (**Exhibit B**); Jie Wang (**Exhibit C**); Mi Xu (**Exhibit D**); Jun Du

(**Exhibit E**); Minli Zhang (**Exhibit F**); Linda Lin (**Exhibit G**); and Eric Gu (**Exhibit H**). (collectively, the “ZHP Declarations”):

1. **ZHP00305868** ([ECF No. 638, Ex. 4](#)): A supplier report dated January 31, 2018, designated as “CONFIDENTIAL INFORMATION”, which describes non-public, proprietary production practices and operating procedures unrelated to the claims at issue in this litigation. *See* Index at 1 (citing Ge Decl. ¶ 3).
2. **ZHP00385769** ([ECF No. 638, Ex. 5](#)): An internal deviation investigation report dated August 27, 2018, designated “RESTRICTED CONFIDENTIAL INFORMATION”, which details non-public, proprietary manufacturing processes. *See id.* at 2 (citing Ge Decl. ¶ 4).
3. **ZHP00479762** ([ECF No. 638, Ex. 7](#)): Confidential customer communications designated “RESTRICTED CONFIDENTIAL INFORMATION”, which detail proprietary specifications and testing methods for impurities. *See id.* at 3 (citing Wang Decl. ¶ 3).
4. **ZHP00493010** ([ECF No. 638, Ex. 8](#)): Confidential communications between the ZHP Parties and their customer designated “RESTRICTED CONFIDENTIAL INFORMATION” that describe

proprietary chromatography testing methods and procedures. *See id.* at 4 (citing Xu Decl. ¶ 3).

5. **ZHP00423144 (ECF No. [638](#), Ex. 6)**: Confidential customer communications designated “CONFIDENTIAL INFORMATION”, which detail sensitive, non-public information regarding testing. *See id.* at 5 (citing Wang Decl. ¶ 4).
6. **PRINBURY00129588 (ECF No. [685](#), Ex. B)**: A draft response to inspection observations by the United States Food & Drug Administration (“FDA”) designated “CONFIDENTIAL INFORMATION”, which contains internal comments not intended for public dissemination and details the ZHP Parties’ sampling and testing procedures, internal impact assessments, and corrective and protective actions taken in response to the FDA’s observations. *See id.* at 6 (citing Ge Decl. ¶ 5).
7. **ZHP00076700 (ECF No. [685](#), Ex. C)**: Confidential communications between the ZHP Parties and their tax preparer for purposes of obtaining tax advice, which have been designated “CONFIDENTIAL INFORMATION” and disclose highly sensitive, tax preparation information not available to the public nor at issue in this litigation. *See id.* at 7 (citing Du Decl. ¶ 1).

8. **PRINSTON00083640** (ECF No. [685](#), **Ex. E**): An FDA pre-approval establishment inspection report for the period of June 24, 2019 through June 28, 2019 designated “RESTRICTED CONFIDENTIAL INFORMATION” that describes in extensive detail the ZHP Parties’ manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 8 (citing Zhang Decl. ¶ 3).
9. **PRINSTON00077836** (ECF No. [685](#), **Ex. F**): A module dated September 20, 2007 designated “RESTRICTED CONFIDENTIAL INFORMATION”, which details proprietary manufacturing systems for valsartan. *See id.* at 9 (citing Lin Decl. ¶ 3).
10. **PRINSTON00082994** (ECF No. [685](#), **Ex. H**): An FDA establishment inspection report dated August 9, 2013 and designated “RESTRICTED CONFIDENTIAL INFORMATION”, which describes in extensive detail the ZHP Parties’ manufacturing operations, volume of finished dosage form products and active product ingredients (“APIs”) for sale to the U.S. market, plans to develop future products, and the facility’s manufacture of drug products not at issue in this litigation. *See id.* at 10 (citing Zhang Decl. ¶ 4).

11.**ZHP00107709** ECF No. [685](#), **Ex. I**): A copy of an FDA establishment inspection report dated August 13, 2014, designated “RESTRICTED CONFIDENTIAL INFORMATION”, which describes in extensive detail the ZHP Parties’ manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 11 (citing Ge Decl. ¶ 6).

12.**PRINSTON0074125** (ECF No. [685](#), **Ex. J**): A copy of an FDA establishment inspection report dated August 13, 2014, designated “RESTRICTED CONFIDENTIAL INFORMATION”, which describes in extensive detail the ZHP Parties’ manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 12 (citing Ge Decl. ¶ 6).

13.**PRINSTON00083026** (ECF No. [685](#), **Ex. K**): An FDA establishment inspection report dated September 14, 2015 designated “RESTRICTED CONFIDENTIAL INFORMATION” that describes in extensive detail the ZHP Parties’ manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 13 (citing Zhang Decl. ¶ 5).

14.**PRINSTON00081549** (ECF No. [685](#), **Ex. L**): An FDA inspection report dated January 17, 2017 and designated “RESTRICTED

CONFIDENTIAL INFORMATION” that describes in extensive detail the ZHP Parties’ manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 14 (citing Zhang Decl. ¶ 6).

15.**PRINSTON00081570** ECF No. [685](#), Ex. N): An FDA inspection report dated April 10, 2018 and designated “RESTRICTED CONFIDENTIAL INFORMATION” that describes in extensive detail the ZHP Parties’ manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 15 (citing Zhang Decl. at ¶ 7).

16.**ZHP0000215** (ECF No. [685](#), Ex. P): A business agreement between ZHP and Shanghai Syncores designated “RESTRICTED CONFIDENTIAL INFORMATION”, which contains information regarding the development of a new valsartan manufacturing process. *See id.* at 16 (citing Gu Decl. ¶ 3).

17.**ZHP02579748** (ECF No. [685](#), Ex. Q): Internal meeting notes designated “RESTRICTED CONFIDENTIAL INFORMATION”, which disclose highly sensitive, proprietary commercial information regarding API process optimization strategies. *See id.* at 17 (citing Lin Decl. ¶ 4).

18.**ZHP00494048** (ECF No. [685](#), Ex. S): An internal protocol governing the recall of foreign-grade valsartan API that details the ZHP parties’

recall strategies for testing and evaluating compliance. *See id.* at 18 (citing Ge Decl. ¶ 7).

19.**PRINSTON00162373** (ECF No. [685](#), Ex. R): An excerpt from an FDA establishment inspection report documenting the FDA's inspection of the ZHP Parties' manufacturing facility for the period of July 23, 2018 through August 3, 2018, designated "RESTRICTED CONFIDENTIAL INFORMATION", which describes in extensive detail the ZHP Parties' manufacturing operations pertaining to drug products not at issue in this litigation. *See id.* at 19 (citing Ge Decl. ¶ 8).

20.**ZHP00458585** (ECF No. [685](#), Ex. T): Confidential customer communications designated "RESTRICTED CONFIDENTIAL INFORMATION", which discuss the accuracy of the ZHP Parties; proprietary solvent testing and impurity identification procedures. *See id.* at 20 (citing Xu Decl. ¶ 4).

21.**ZHP00476678**: Confidential customer communications from May 2015 designated "CONFIDENTIAL INFORMATION", which disclose non-public, proprietary customer specification, documentation requirements, and testing procedures. *See id.* at 21 (citing Wang Decl. ¶ 5).

- 22.**ZHP02270194** (ECF No. [685](#), Ex. U): Confidential customer communications designated “RESTRICTED CONFIDENTIAL INFORMATION”, which disclose non-public, proprietary sales targets and forecasting data. *See id.* at 22 (citing Xu Decl. ¶ 5).
- 23.**ZHP01893902** (ECF No. [685](#), Ex. V): Confidential customer communications designated “CONFIDENTIAL INFORMATION”, which disclose non-public, proprietary sales data. *See id.* at 23 (citing Xu Decl. ¶ 6).
- 24.**ZHP00310874** (ECF No. [685](#), Ex. W): Confidential customer communications designated “CONFIDENTIAL INFORMATION”, which reveal proprietary chromatography testing, sampling, and investigation procedures. *See id.* at 24 (citing Xu Decl. ¶ 7).
- 25.**ZHP02125655** (ECF No. [685](#), Ex. X): Confidential customer communications designated “CONFIDENTIAL INFORMATION”, which reveal proprietary chromatography testing, sampling, and investigation procedures. *See id.* at 25 (citing Xu Decl. ¶ 8).
- 26.**ZHP01976459** (ECF No. [685](#), Ex. Z): Confidential customer communications designated “CONFIDENTIAL INFORMATION”, which discuss forecasting data. *See id.* at 26 (citing Xu Decl. ¶ 9).

27. **HUAHAI-US00008050** (ECF No. [685](#), Ex. AA): Confidential customer communications designated “CONFIDENTIAL INFORMATION”, which reveal proprietary information regarding an audit at the Xunqiao site, the scope of the audit, and the customer’s audit procedures. *See id.* at 27 (citing Xu Decl. ¶ 10).
28. **ZHP00183600** (ECF No. [705](#)): An audit plan of the ZHP Parties’ Chuannan site for the period of June 13-14, 2017 designated “RESTRICTED CONFIDENTIAL INFORMATION”, to be conducted by a third party at the request of one of their customers and that discuss non-U.S. Drug Master File (“DMF”) grade valsartan, which is not relevant to the claims at issue in this litigation. *See id.* at 28 (citing Xu Decl. ¶ 11).
29. **ZHP00182575** (ECF No. [705](#)): Confidential customer communications designated “RESTRICTED CONFIDENTIAL INFORMATION”, which contain non-public, proprietary information regarding product testing and relate solely to non-U.S. DMF grade valsartan, which is not relevant to the claims at issue in this litigation. *See id.* at (citing Wang Decl. ¶ 6).
8. The above-referenced documents generally fall into three (3) categories of non-public information:

- a. Non-public documents that refer to the ZHP Parties' proprietary commercial and business interests, including information relevant to the research, development, formulation, and manufacture of their APIs and drug products, which have been designated "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" ("Category 1 Documents");
 - b. Inspection reports prepared by FDA designated "RESTRICTED CONFIDENTIAL INFORMATION" that disclose proprietary, highly-sensitive commercial information ("Category 2 Documents"); and
 - c. Confidential customer communications designated "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" that contain non-public and commercially sensitive information that are subject to confidentiality agreements or other express language requesting restricted dissemination ("Category 3 Documents").
9. These documents contain non-public commercial, financial, and proprietary information, which is believed in good faith by the ZHP Parties to have the potential, if disclosed, for causing significant competitive harm to them in the

form of decreased market share, damaged customer relationships, and litigation costs and contract damages.

CONCLUSIONS OF LAW

10. There exists in civil cases a common law public right to access judicial proceedings and records. *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192 (3d Cir. 2001) (citing *Littlejohn v. BIC Corp.*, 851 F.2d 673, 677-78 (3d Cir. 1988)). Courts, however, have recognized that the presumption of public access is not absolute and may be rebutted. *Republic of the Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 662 (3d Cir. 1991).

11. The party seeking to overcome the presumption of access must show “that the interest in secrecy outweighs the presumption.” *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). To do so, the movant must demonstrate “that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Id.* (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)); *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984)); *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 (3d Cir. 1994).

12. The sealing of confidential documents and information is an accepted practice in the District of New Jersey. *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 653 (D.N.J. 2004). “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” *Littlejohn*, 851 F.2d at 678 (quoting *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 598 (1978)).

13. Under Local Rule 5.3(c), material may be filed and maintained under seal upon a showing of good cause. *See* L. CIV. R. 5.3(c); *Vista India, Inc. v. Raaga, LLC*, No. 07-cv- 1262, 2008 WL 834399, at *3 (D.N.J. Mar. 27, 2008). The moving party must show that the following factors weigh in favor of sealing the information at issue: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available. Local Rule 5.3(c)(3). This Court has discretion in balancing the factors for and against access to court documents. *See Pansy*, 23 F.3d at 781.

14. Factors weighing in favor of confidentiality are: (1) the information to be protected includes genuinely confidential information such as proprietary materials, or information that could give unfair advantage to a competitor; (2) the documents were produced under the auspices of an existing confidentiality order

upon which the parties relied; (3) the materials are not subject to freedom of information laws or statutes requiring disclosure of public documents; and (4) the party to benefit from the order is a private entity, not a public official seeking protection from “legitimate public scrutiny.” *Pansy*, 23 F.3d at 788-91. The scale is tipped in favor of confidentiality where the parties relied on a prior confidentiality order. *See, e.g., Rutigliano v. Appleton Papers, Inc.*, No. 90-1432, 2000 WL 1705152 at *5 (D.N.J. Oct. 6, 2000) (public disclosure in product liability action should not be compelled where defendant produced material in reliance on a confidentiality order).

15. Each category of documents will be examined in turn.

The Category 1 Documents

16. The documents identified in Category 1 of the Index refer to non-public, proprietary technical information, protocols, and processes relating to the research, development, formulation, and manufacture of the ZHP Parties’ APIs and drug products, which are presently unavailable to the public. These documents have been designated “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” pursuant to the Protective Order entered in this matter, which provides for the confidential treatment of this type of proprietary information.

17. This Court, and Courts construing New Jersey law, have repeatedly recognized the need to protect from disclosure non-public, commercially sensitive and proprietary information, particularly regarding research, development, and manufacturing specifics. *See, e.g., Bock v. Pressler & Pressler, LLP*, No. 2:11-cv-7593, 2014 WL 1233039, at *3 (D.N.J. March 25, 2014) (sealing information where moving party demonstrated private interest in protecting “business agreements, trade secrets, or commercial information” from public disclosure); *Mars, Inc. v. JCM Am. Corp.*, No. 1:05-cv-3165, 2007 WL 496816, at * 2 (D.N.J. 2007) (stating, “[c]ourts generally protect materials containing trade secrets or other confidential research, development, or commercial information to prevent harm to a litigant’s standing in the marketplace.”); *In re Gabapentin*, 312 F. Supp. 2d at 664 (“A well-settled exception to the right of access is the ‘protection of a party’s interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.’”) (citation omitted).

18. Thus, despite the “common law public right of access to judicial proceedings and records,” courts will generally grant motions to seal when the materials contain “trade secret[s] or other confidential research, development, or commercial information’ to prevent harm to a litigant’s standing in the marketplace.” *In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001); *Vista India*,

Inc., 2008 WL 834399, at *2 (citation and internal quotation marks omitted); Fed. R. Civ. P. 26(c)(1)(G).

19. In particular, this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of Abbreviated New Drug Applications (“ANDAs”), DMFs, formulations, and other confidential testing by drug manufacturers. *See, e.g., Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *3 (D.N.J. Dec. 6, 2018) (stating, “this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers”); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 667 (affirming magistrate judge’s denial of motion to unseal documents that contained information relating to defendant’s ANDA, DMF, processes, formulations, and testing); *Valeant Pharm. Luxembourg S.à r.l. v. Actavis Labs. UT, Inc.*, No. 2:16-cv-4344, 2018 WL 1469050, at *3 (D.N.J. March 26, 2016) (same); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at *2 (D.N.J. Aug. 7, 2015) (sealing documents that producing party designated highly confidential because they “contain or reflect information contained in or derived from ANDAs, as well as highly proprietary business

information regarding the development, formulation, manufacture and sales of ANDA products”); *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 U.S. Dist. Lexis 212, at *6-8 (D.N.J. Jan. 3, 2017) (sealing confidential manufacturing and research and development processes and information as well as internal documents, such as laboratory notebooks).

20. The documents that the ZHP Parties seek to seal that have been designated “CONFIDENTIAL INFORMATION”—reports describing the ZHP Parties’ proprietary production practices and standard operating procedures and communications with customers regarding testing procedures, as described more fully in the Index and the ZHP Declarations—contain the kind of confidential and commercially sensitive information that Courts typically protect from public disclosure. Disclosure of this information would result in competitive harm to the ZHP Parties by generating unfounded concern among the public about the sufficiency of their operating procedures as the result of inquiries that have been addressed or are unrelated to the current litigation. It also would allow their competitors to exploit that confusion, further disadvantaging the ZHP Parties during the pendency of the FDA’s current import ban related to the Chuannan facility.

21. The documents that the ZHP Parties seek to seal that have been designated “RESTRICTED CONFIDENTIAL INFORMATION” detail

proprietary manufacturing processes for multiple different APIs and drug products, the components, the formation steps, solvents used, and proposed process changes. Disclosure of such non-public, commercially sensitive information, particularly to the ZHP Parties' direct competitors, could cause significant commercial harm by allowing them to benefit from their internal research and development while they are competitively disadvantaged as a result of the FDA's current import ban related to the Chuannan facility.

22. The ZHP Parties have a legitimate interest in maintaining the confidentiality of commercially sensitive business information, including research, development, and technical information related to the components and formulation of its APIs and drug products. The ZHP Parties have invested significant resources into the development of its APIs and drug products with the expectation that documents containing such competitively sensitive and proprietary information would be confidential and remain unavailable to competitors. There is substantial public interest in ensuring that this non-public information relating to the ZHP Parties' API and drug products remain confidential and will not become public at a later date.

23. The clearly defined and serious injury that would result should the proposed Order to seal not be entered is that the ZHP Parties would suffer significant competitive harm as a result of the disclosure of valuable proprietary

commercial information to the public and/or their competitors. With respect to the documents designated as “CONFIDENTIAL INFORMATION”, disclosure would generate unfounded concern among the public and allow their competitors to exploit that concern during the pendency of the FDA’s current import ban related to the Chuannan facility. With respect to the documents designated “RESTRICTED CONFIDENTIAL INFORMATION,” disclosure would provide direct competitors of the ZHP Parties public insight into their proprietary research, development, proposed process changes, and technical information related to the components and formulation of its APIs and drug products. Valuable business and trade secrets created at substantial expense by the ZHP Parties would be lost, while its competitors would unjustly benefit.

Category 2 Documents

24. These documents are FDA establishment inspection reports of the ZHP Parties’ manufacturing facilities. The reports evaluate the facilities’ readiness to commercially manufacture numerous APIs and drug products not at issue in this litigation, and describe in detail manufacturing operations; standard operating procedures; proprietary training programs; supplier qualification procedures; process validation reports; deviation investigation procedures; and analytical testing methods relating to numerous unrelated APIs and drug products. They

have been designated “RESTRICTED CONFIDENTIAL INFORMATION” pursuant to the Protective Order entered in this matter, which provides for the confidential treatment of this type of proprietary information.

25. For the reasons set forth in Paragraphs 18-20 *supra*, the Category 2 Documents contain the kind of confidential and commercially sensitive information that Courts typically protect from public disclosure.

26. The ZHP Parties have a legitimate interest in maintaining the confidentiality of the FDA reports. The ZHP Parties have invested significant resources into the development and maintenance of their drug manufacturing facilities with the expectation that documents evaluating their commercial readiness and capabilities would remain unavailable to competitors. Disclosure of these reports would, in effect, provide direct competitors of the ZHP Parties with a guidebook to their manufacturing facilities, procedures and protocols, and any observed deviations—no matter how old or irrelevant—as to multiple APIs and drug products not at issue in this litigation. This level of disclosure would result in significant competitive harm to the ZHP Parties.

27. Disclosure of the information sought to be sealed here could cause significant competitive harm because it would give direct competitors of the ZHP Parties an unfair advantage in a highly competitive marketplace, particularly while

the ZHP Parties are prohibited from importing products into the U.S. market by the FDA.

28. The clearly defined and serious injury that would result should the proposed Order to seal the Category 2 Documents not be entered is that valuable commercial and proprietary manufacturing data created at substantial expense by the ZHP Parties will be lost and competitors would unjustly gain access to them.

Category 3 Documents

29. These documents are customer communications that have been designated “CONFIDENTIAL INFORMATION” or RESTRICTED CONFIDENTIAL INFORMATION” that contain non-public and commercially sensitive information and are subject to language restricting the dissemination of the communication and/or confidentiality agreements.

30. The ZHP Parties have a legitimate interest in maintaining the confidentiality of customer communications, particularly where the customers themselves clearly intended to restrict the distribution of their communications to the intended recipients through the use of disclaimers or restrictive language in their emails.

31. Disclosure of the communications sought to be sealed here, without prior authorization from the customers with whom the communications were made, would cause significant competitive harm by forcing the ZHP Parties to

deliberately (1) disregard the express intention of their customers to restrict the dissemination of their communications, or (2) breach outstanding confidentiality agreements with their customers, thus jeopardizing customer relationships.

32. The clearly defined and serious injury that would result should the proposed Order to seal the identified documents not be entered is the loss of longstanding customer relationships as well as risking significant financial harm in the form of litigation costs and contract damages. This injury is particularly needless since many of the challenged communications discuss non-U.S. DMF grade valsartan, which is not relevant to the claims at issue in this litigation.

33. In accordance with the Local Rules, the Index identifies each document that contains the information the ZHP Parties seek to seal. In the Index, the ZHP Parties describe with particularity: (a) the nature of the materials; (b) the legitimate private or public interest which warrants the relief sought; (c) the clearly defined and serious injury that would result if the relief sought is not granted; (d) why a less restrictive alternative to the relief sought is not available; (e) any prior order sealing the same materials in the pending action; (f) the identity of any party or nonparty known to be objecting to the sealing request; (g) the materials to which there is an objection; (h) the basis for the objection; and (i) if the material or information was previously sealed by the Court in the pending action, why the materials should not be maintained under seal. *See* Index.

34. There is no less restrictive alternative available other than to seal the documents identified in the Index. The ZHP Parties seek to seal only those documents identified in the Index that disclose the parties' sensitive and proprietary business information. In an effort to narrowly tailor the information they propose remain sealed, the ZHP Parties have reviewed and analyzed each exhibit, in order to specifically identify exactly which documents should remain sealed. This is evidenced by the detailed Index the ZHP Parties have submitted in support of their Motion to Seal. *See* Index.

35. There is no prior order sealing the same materials in the pending action. (*See* Index).

36. Plaintiffs have objected to the sealing request on the grounds that they do not believe that confidential treatment is justified under the Protective Order in light of what they describe as a public health interest. *See Avandia*, 924 F.3d at 671 (identifying “various factors that courts may consider when determining whether good cause exists and, by extension, whether a protective order should issue,” including, “whether confidentiality is being sought over information important to public health and safety.”) But in *Avandia*, Court advised that these factors were discretionary; not mandatory, and should be considered as part of a balancing test. *See id.* Plaintiffs have not articulated how the designated materials even relate to, let alone are important to public health and safety. Nor have they

articulated how that relation outweighs the ZHP Parties' interest in safeguarding its proprietary commercial information. Whereas here, the ZHP Parties have detailed how the disclosure of their proprietary testing methods, processes, protocols, manufacturing capacities, and internal reporting methods to the public and their direct competitors would seriously harm their ability to compete, especially following the lifting of the FDA's current import ban.

37. The Court, having considered this matter pursuant to Local Civil Rule 5.3, and the submissions in support of the Motion, finds that the ZHP Parties have satisfied their burden of proving under Local Civil Rule 5.3(c) and applicable case law, that the information sought to be sealed by the ZHP Parties contains CONFIDENTIAL and/or RESTRICTED CONFIDENTIAL information that warrants sealing.

38. Pursuant to the foregoing Findings of Fact and Conclusions of Law, and for good cause shown:

IT IS on this _____ day of _____, 2021, hereby

ORDERED that the ZHP Parties' Motion to Seal is hereby **GRANTED**;
and

IT IS FURTHER ORDERED that the documents identified in Exhibit A to the Declaration of Kelly A. Bonner in Support of the Motion to Seal contain Confidential and/or Restricted Confidential Information and shall remain sealed.

IT IS FURTHER ORDERED that a copy of this Order shall be served on all counsel of record within ____ days of Plaintiffs' liaison counsel's receipt of this Order.

Dated: _____

By the Court:

Hon. Karen Williams,
United States Magistrate Judge

Hon. Thomas Vanaskie, (Ret.)
Special Discovery Master